

Notice of Allowability**Application No.**

09/870,483

Examiner

Taylor Victor Oh

Applicant(s)

OKUDA ET AL.

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/29/04.
2. ☒ The allowed claim(s) is/are 20-42, as renumbered in claims 1-23.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

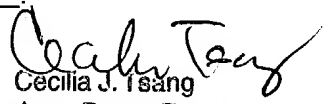
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 3/24/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 10/1/04
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Cecilia J. Tsang
Supervisory Patent Examiner
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Examiner's Amendment and Reasons of Allowance

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with an attorney of record, Mr. William R. Lambert on 10/1/2004 .

I. The application has been amended as follows:

In claim 27, line 3 on page 3 (a preliminary amendment on 6/29/04):

The phrase"--consisting essentially of--" before the number " 5 " has been deleted and replaced with "of" .

In claim 27, line 4 on page 3 (a preliminary amendment on 6/29/04):

The phrase"--consisting essentially of--" before the number " 5 " has been deleted and replaced with "of" .

In claim 27, line 6 on page 3 (a preliminary amendment on 6/29/04):

The phrase"--consisting essentially of--" before the number " 5 " has been deleted and replaced with "of" .

In claim 28, line 2 on page 3 (a preliminary amendment on 6/29/04):

The phrase"--consisting essentially of--" before the number " 5 " has been deleted and replaced with "of" .

II. The following is an examiner's statement of reasons for allowance:

- The objection of claim 26 for the minor informality has been withdrawn due to the correction made in the amendment ;
- The rejection of claims 27-28 and 36 under 35 USC 112, second paragraph, has been withdrawn due to the modification made in the amendment;
- The close references for the current invention are Kawabe et al (US 5,763,652) and Susumu et al ((JP10059895: translated version).

Kawa et al teaches a process for producing an alpha-hydroxycarboxylic acid by hydrolyzing an alpha nitrile compound in the presence of an acidic acid. The amount of the acidic catalyst is selected from a range of 0.75 to 10 moles per mole of the nitrile compound and the amount of water relative to 1 mole of the nitrile compound is 1.5 to 50 moles. The hydrolysis reaction can be carried out at a temperature of 50 to 150⁰ C in an inert solvent .

Susumu et al teaches a process of producing a 4-phenyl mandelic acid by reacting 4-phenyl benzaldehyde, toluene, concentrated hydrochloric acid, and potassium cyanides

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in water at 15 to 20 ° C; the concentrated hydrochloric acid has been introduced in the reaction mixture and heated at 75-80 ° C .

However, the instant invention differs from the prior art in that neither Kawabe et al nor Susumu et al teach that optical purity is a parameter to be optimized or that the conditions of the hydrolysis reaction can impact the optical purity of the alpha-hydroxycarboxylic acid during the process ; Susumu et al do not address the synthesis or crystallization of mandelic acid derivatives having high optical purity and don not recognize optical purity as being a results-effective variable and therefore, there is no motivation to combine the prior art , thereby unable to arrive at the present invention; furthermore, the claimed ratio of the volume of the aqueous solution to that of the non-miscible organic solvent ranges from 1: 0.05 to 1:1, the claimed crystallization takes place at a rate of 0.5 ° C/min and the crystalline optically active alpha-hydroxycarboxylic acid exhibits a packing density of 0.5 g/cm³. In addition, unless all limitations of the claims are met, there is no prior art rejection. See In re Zurko 59 USPQ 2d 1690 (Fed Cir. 1991) and In re Lee, 61 USPQ 1430 (Fed Cir. 1991).

Therefore, the claimed invention would not have been obvious to the person with an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning the communication after allowance such as sending all post-allowance correspondence should be directed to "Box Issue Fee" or faxed directly to PUBS at 703-305-8755. This will expedite the process of these papers.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John
10/1/04

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